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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Yaron Keidar

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT

PAPER NUMBER

3739

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/621,988	Applicant(s) KEIDAR, YARON	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 15-45 is/are pending in the application.
 4a) Of the above claim(s) 17-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 15 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/17/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Claims 17-45 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 1, 2005.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcus et al (5,295,484) in view of the teachings of Panescu et al (2003/0078509) and Webster, Jr. (5,827,278).

Marcus et al discloses a catheter for mapping and ablating cardiac tissue, the catheter having an ultrasound transducer mounted at the distal end. The transducer may take a variety of shapes, and includes a back surface mounted to the catheter for directing energy in a forward direction. In Figures 8 and 9, the transducer is mounted to the distal end and has a flat face for directing energy forward (see col. 7, lines 50-55). Figure 6 shows a rectangular-faced transducer with the back surface mounted in the catheter body. Marcus et al also disclose electrodes on the distal catheter surface for sensing a location (e.g. through mapping) in the heart. However, Marcus et al do not specifically disclose that the electrodes function as sensors to sense a location and an

orientation of the transducer within the patient, and Marcus et al also fail to specifically disclose a steering mechanism used to deflect the catheter. With regard to the various sizes for the transducer and the spacing for the sensors, the examiner maintains that such parameters would be a matter of obvious design choice dependent on the particular procedure. It is noted that applicant's specification has not indicated any particular criticality or unexpected result associated with these values.

Panescu et al, as addressed in previous Office actions, also disclose a catheter for the mapping and ablation of cardiac tissue. In particular, Panescu et al teach that it is advantageous to provide such a catheter system with a sensor means to precisely locate the catheter device, as well as determine the orientation of the catheter (and inherently it's components) within the body. See paragraphs [0103-0104].

Regarding the deflecting means, the examiner maintains that steering wires are generally very well known in the art of ablation catheters, particularly cardiac ablation catheters, for controlling the placement of the device on tissue. Webster, Jr. discloses another ablation catheter and specifically discloses a steering mechanism including a control handle at the proximal end of the catheter body, and a deflection wire (30) extending through the catheter body. The deflection wire (30) has a distal end (42) fixed to the catheter distal end. The deflection wire is anchored at a position that is off-axis to the central axis of the catheter body (Figure 6). The examiner maintains that one of ordinary skill in the art would recognize that the steering wire may be located at any desired off-axis position to control the steering of the catheter relative to the ablation element that would be treating tissue. For example, the Webster, Jr.

embodiment of Figure 6 would allow for steering of the catheter in a direction to the right as you look at the catheter. One of ordinary skill in the art would recognize that adding such a steering mechanism to the Marcus et al catheter having the flat transducer (Figures 6 and 7) would allow the catheter to be steered in a desired direction. The particular direction the Marcus et al catheter would be steered would be an obvious design consideration for one of ordinary skill in the art, and the skilled artisan would obviously know how to locate the steering wire relative to the tip to provide the desired bending plane.

To have provided the Marcus et al catheter with a location sensor means to precisely determine the location and orientation of the catheter within the body to assure treatment of a desired tissue target would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Panescu et al. To have further provided the Marcus et al catheter with a deflection wire to control the placement and orientation of the transducer within the body would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Webster, Jr. The specific connection point for the steering wire is deemed to be an obvious design consideration as one of ordinary skill in the art would be capable of determining the best location to provide the optimal steering plane for aligning the transducer relative to tissue.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marcus et al ('484), Panescu et al ('509) and Webster, Jr. ('278) as applied to claim 1 above, and further in view of the teaching of Chandrasekaran et al (6,394,956).

The combination of the Marcus et al catheter with the Panescu et al and Maguire et al teachings has been addressed previously. Marcus et al disclose electrodes on the end of the catheter, but fail to specifically disclose the ultrasound transducer mounted on the surface of the electrode. Rather, the electrodes are provided in proximity to the transducer.

Chandrasekaran et al disclose another mapping and ablation catheter and specifically teach that it is known to mount an ultrasound transducer (34) directly to an electrode (38) at the distal end of the catheter assembly. Such a mounting allows the use of the transducer in direct relationship with the electrode.

To have provided the Marcus et al device with a tip electrode and the transducer mounted to the transducer, as fairly taught by Chandrasekaran et al, to allow for the use of RF and ultrasound energy at the same location would have been an obvious consideration for one of ordinary skill in the art.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marcus et al ('484) and Panescu et al ('509) and Webster, Jr. ('278) as applied to claim 1 above, and further in view of the teaching of Crowley et al (6,004,269).

Again, the combination of the Marcus et al catheter with the Panescu et al and Maguire et al teachings has been addressed. Neither catheter specifically provides for a fluid channel to provide an irrigant to tissue.

Crowley et al disclose another ablation catheter that includes an ultrasound transducer and electrodes. In particular, Crowley et al teach of the advantages of

Art Unit: 3739

providing a flushing or ablation enhancement solution through a lumen in the catheter (col. 10, lines 38-45).

To have provided the Marcus et al catheter, as modified by the teaching of Panescu et al, with a fluid lumen to provide an irrigant and/or ablation enhancement fluid to enhance the ablation of tissue would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Crowley et al.

Response to Arguments

Applicant's arguments filed February 25, 2008 have been fully considered but they are not persuasive.

Applicant contends that since the Webster, Jr. device includes ring electrodes that enable energy delivery to tissue in any orientation, that there is no proper suggestion to provide a steering wire as taught by Webster, Jr. to a catheter having a direction oriented energy delivery element. This argument is not found persuasive by the examiner. The examiner maintains that one of ordinary skill in the art would readily recognize, based on the suggestion by Webster, Jr., that it is advantageous to provide a steering mechanism on any heart ablation catheter. The heart is a relatively organ, compared to the catheter, and Webster, Jr. teaches of the advantages of providing a steering mechanism that would allow for the location of the operative tip at a desired location. Again, the examiner maintains that whether the delivery means is directional specific or circumferential, there are still clear advantages of providing a steering wire for locating the operative element(s) at a desired location. Further, the examiner also maintains that one of ordinary skill in the art would be obviously be able of determining

Art Unit: 3739

preferred steering wire attachment locations given an ablation device that had a specifically oriented ablation element. That is, there would be no undue experimentation necessary to determine optimal locations for the attachment of a steering wire to appropriately control the deflection of a catheter having an oriented ablation mechanism on the tip such that the device may be directed and oriented to the proper tissue site for treatment. Webster, Jr. is merely cited as a teaching that it is generally known to use steering wires to control the deflection of a cardiac ablation catheter so as to locate the operating tip at a desired tissue site. It remains the examiner's position that a skilled artisan would be capable of using such a teaching to effectively modify the Marcus device to employ the same steering advantages.

Applicant has not substantively argued the merits of the combination of the Panescu et al teaching to the rejected claims, nor has the applicant argued subsequent obviousness rejection of claims dependent from claim 1. The examiner maintains the rejections of record are tenable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 3739

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739